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10/066,057	01/31/2002	Michael B. Zemel	UTR-104D1	8306

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EXAMINER	
FISHER, ABIGAIL L	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/066,057	ZEMEL ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,28-37,41-44,46-53,55,57,59-62 and 64-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,28-37,41-44,46-53,55,57,59-62 and 64-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on November 10 2008 is acknowledged. Claims 2-4, 7-27, 38-40, 45, 54, 56, 58 and 63 were/stand cancelled. Claims 65-72 were added. Claims 1, 5-6, 28-37, 41-44, 46-53, 55, 57, 59-62, 64-72 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 10 2008 was considered by the examiner.

Claim Objections

The objection claim 62 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is **withdrawn** in light of Applicants' amendments filed on November 10 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 5-6, 27-37, 41-44, 46-51 and 53-55, 57, 59-63 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants' amendments and arguments filed on November 10 2008.

Claims 52, 64, 67 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the reply filed on October 4 2005, applicant amended claim 52 to be directed to a daily amount of at least about 1000 mg. Claims 61-64 were added. Claim 64 claims the amount of calcium is at least about 1000 mg per day. Once again applicant does not have support for these amendments. About 1000 is not close to supported values of 773 or 1346.

In the reply filed on November 10 2008, applicants added new claim 72 which recites a caloric intake in the range of about 2000 to about 2500 kcal per day. However, applicants do not have support for this range. The specification (page 9) indicates that the caloric intake is about 200 to about 2500 kcal per day. Preferred

ranges are from about 300 to 2400 kcal per day, 500 to 2200 kcal per day, more preferably 700 to 2000 kcal per day even more preferably 900 to 1700 kcal per day and most preferably 1100 to 1500 kcal per day. However, none of these ranges contemplates 2000 kcal as the lower limit of the range. Therefore, applicants do not have support for the range of 2000 kcal to 2500 kcal per day wherein 2000 kcal is the lower limit of the caloric range.

Response to Arguments

Applicants argue that the value of 1000 mg calcium is supported at page 2 line 29-page 3 line 2 of the specification as filed and as set forth in Table 4 as it provides support for the full range of values in between those listed, which encompasses 1000 mg calcium.

Applicants' arguments filed November 10 2008 have been fully considered but they are not persuasive.

Firstly, because applicants have support for the range of 745 to 1459 mg does not mean that they have support for the specific dosage of 1000 mg because it falls within the supported range. **Note: MPEP 2163.05.** There is not a working example that specifically teaches this amount nor does the range of 745 to 1459 mg clearly disclose to the skilled artisan that the inventors considered this amount to be part of their invention.

Secondly, the other portion of the specification that applicants point to for support states that recent data has shown that increasing dietary calcium from 400 to 1000

mg/day results in a 4.9 kg reduction of body fat in humans over the course of one year. Therefore, applicants only have support for 1000 mg in conjunction with this specific amount of body fat reduction. Subsequently, applicants do not have support for 1000 mg/day with the currently pending claims which a method of inducing weight loss which includes all values of body fat reduction. Therefore, the current claim scope is different than which applicants have support for 1000 mg/day.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 5-6, 27-37, 41-44, 46-55, 57, 59-64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of applicants amendments and arguments filed on November 10 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-6, 28-30, 32, 41-44, 46-53, 55, 57, 59-62, 64-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Study: Calcium May Curb Weight Gain in Young Women (http://www.sciencedaily.com/releases/1999104199042107360 8.htm, April 21 1999, referred to in the Office action as "Science Daily", cited in PTO Form 1449) in view of Summerbell et al. (BMJ, cited in the Office action mailed on November 26 2007).

Applicant Claims

Applicant claims a method comprising in combination, during a period of time administering therapeutically effective amount of calcium in an amount of about 773 mg per day to an obese individual suffering from at least Grade I obesity with a BMI values of about 25.0 and restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein the individual loses weight during the period of time.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Science Daily is directed to a study of the effect of calcium on weight gain. It is disclosed that when overall calorie consumption is account for, calcium not only helps to keep weight in check but can be associated specifically with decreases in body fat (paragraph 1). It is disclosed that when women of the study consumed a diet of 1900 calories or less, those who consumed an average of 1000 mg of calcium per day showed an overall decrease in body weight (paragraph 4 and 5) especially when compared to women those consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period (paragraph 4). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8). It is disclosed that women who consume calcium from dairy products or who consume at least 1000 mg per day of calcium may reap the most benefit (abstract, second paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Science Daily does not specify utilizing calcium to induce weight loss in obese women. However, this deficiency is cured by Summerbell et al.

Summerbell et al. is directed to weight reducing diets. The diets of the trial were directed to reducing weight in patents with a body mass index (BMI) greater than 27 (abstract). Three diets were administered. Diet 1 was a control. Diet 2 was a milk only diet. Diet three was a milk plus diet, which consisted of milk with the addition of unlimited amount of a single food (page 1488, interventions). It is disclosed that in the milk only diet patients achieved the highest overall mean weight loss (page 1489, first paragraph).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and utilize calcium in a method of inducing weight loss in an individual suffering from obesity. One of ordinary skill in the art would have been motivated to utilize calcium in this type of method because Science Daily indicates that calcium decreases body fat. Therefore, it would have been obvious to utilize calcium in an individual who needs to loose body fat such as an obese person. Furthermore Summerbell et al. indicates that this type of administration has been shown to induce weight loss in obese patients.

It would have been obvious to one of ordinary skill in the art to vary the amount of calcium to determine the optimum of amount of calcium for each individual. It would

have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the administration of at least 57 or 102 servings of dairy per month (instant claims 1, 10, 12, 19, 50, 61 and 69-71), the amount of calcium instant claimed and that of Science Daily is the same (at least 1000 mg/day). Therefore, depending on the source of the calcium it would have been obvious to one of ordinary skill in the art to determine the appropriate number of servings to consume in order to reach the required daily amount of at least 1000 mg/day.

Regarding instant claims 59 and 60, Summerbell et al. teach individuals with a BMI greater than 27, which would include those with Type II and Type III obesity. Furthermore, it would have been obvious to one of ordinary skill in the art to administer calcium to an obese individual because Science Daily teaches that calcium causes weight loss. Obese individuals are a patient population that is in need of weight loss. Depending on the individual, the type of obesity will vary.

Regarding the claimed amount of calcium, Science Daily teaches that administration of 1000 mg/day provides more of an overall decrease in body weight as compared to the lower dose of 780 mg. Therefore, it would have been obvious to one of ordinary skill in the art to manipulate the dosage of calcium in order to determine the optimal amount that produces the desired decrease in body weight.

Response to Arguments

Applicants argue that (1) Science Daily focused solely on women of normal weight and does not disclose teach or suggest that calcium has any effect on obese individuals. Applicants argue that (2) the women in the Science Daily study followed no specific diet. Applicants argue that (3) the Science Daily study could not demonstrate that calcium and not another component of milk cause the observed weight benefits and that the Science Daily found non-dairy calcium had no effect on body weight. Applicants argue that (4) the publication "Lin Study" casts doubts on the authors' conclusion that calcium caused the observed weight changes. Applicants argue that (5) Summerbell's conclusion that the best diet strategy would be to rotate diets would lead one away from the teachings of the present invention.

Applicants' arguments filed November 10 2008 have been fully considered but they are not persuasive.

Regarding applicants first argument, Science Daily teaches that administration of 780 mg of calcium there was no increase in body fat or loss of body fat mass over the two year period. Therefore, these patients essentially maintained their weight. Women

who consumed less than 780 mg gained body fat mass over the two year period. However, women who consumed 1000 mg of calcium per day showed an overall decrease in body weight. Since Science Daily clearly teaches administration causes fat loss, it would have been obvious to one of ordinary skill in the art to administer calcium to those who needs to lose fat the most, obese people. Furthermore, Summerbell et al. supports this notion as it is taught that administration of a calcium rich diet (a milk only diet) caused weight loss in obese individuals. Therefore, one of ordinary skill in the art would expect that administration of calcium to obese individuals would work as it does in normal weight individuals regardless of purported endocrine differences between individuals of normal weight and obese individuals.

Regarding applicants second argument, the examiner does not see where Science Daily states this. What is taught by science is daily is that women who consumed less than 1900 calories per day but too little calcium showed an increase in body fat mass. Those that consumed less than 1900 calories and a moderate amount of calcium resulted in no increase in body fat or loss in body fat mass. Those who consumed less than 1900 calories but 1000 mg of calcium saw a decrease in body weight but those who consumed more than 1900 calories did not benefit. Therefore, Science Daily clearly teaches that both calorie consumption and the amount of calcium intake are important, which would make sense. If a person of normal weight consumed too many calories they would necessarily gain weight as calorie consumption is directly related to weight gain. Furthermore, in order to be an accurate study, the calorie intake of those participants in the Science Daily study should not be too restrictive so as to

show that the weight loss is directly related to calcium consumption and not due to a low caloric intake. However, the caloric intake taught by Science Daily of 1900 calories reads on the instantly claimed range of about 200 to about 2500 kcal per day.

Regarding applicants third argument, Science Daily does not state that non-dairy sources had no effect, what Science Daily states is that dairy sources showed "**more benefits**" of weight control measures than those who primary used non-diary sources. This does not mean that there was no benefit just that there was more of a benefit with the dairy sources. The reasons for this the article postulates is that the difference may be due to the fact that women who utilize the non-dairy sources would have to eat significant amount of the non-dairy foods to produce these effect or it may suggest that there is something in milk that works to helps regulate body weight . However, the article clearly states that it is the calcium that causes the effect on body weight. As evidenced by Bronner et al. (Journal of Nutrition, 1999), dietary sources of calcium such as spinach is low and poorly soluble where as calcium absorption from milk is high (page 11, left column, first paragraph). Therefore, these non-dairy sources may just not be as soluble of sources of calcium, which would explain Science Daily statement that those who utilize the non-dairy sources would have to consume significant amounts to get the effect. Nonetheless, all of the teachings of Science Daily specifically indicate that it is the calcium that causes the reduction in weight.

Regarding applicants fourth argument, the examiner has read the submitted "Lin Study". Lin clearly indicates that calcium has an impact on weight regulation in women during a two year exercise intervention trial (page 757, discussion). Lin also teaches

that several studies support that higher calcium intake can reduce weight (page 758, right column, second paragraph). While the applicants have pointed to section in which Lin attempts to hypothesize a rationale for the suggestion between calcium intake and weight changes, the authors summarize that higher calcium intakes were associated with weight loss, specifically fat mass. Therefore, the Lin study does not dispute the assertion by the Science Daily article that calcium causes a reduction in weight. Subsequently, one of ordinary skill in the art would have been motivated to utilize calcium in a method of reducing weight by administering calcium as that is what Science Daily teaches to one of ordinary skill.

Regarding applicants fifth argument, Summerbell et al. makes this statement because a milk only diet for a long time would cease to be novel and therefore compliance with the diet would fall. The data presented by Summerbell et al. showed that obese patients lost the most with a milk only diet; however patients who were on a milk plus diet still lost weight. Therefore, a diet rotation would not preclude an obese patient from neither losing weight nor utilizing the teachings of Summerbell et al. and Science Daily to teach to one of ordinary skill that the utilization of calcium in your diet will result in weight loss.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 31, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Science Daily in view of Summerbell et al. and in further view of Dietary Supplement Fact Sheet (cited in PTO Form 1449).

Applicant Claims

Applicant claims that the calcium is contained in salmon, tofu, spinach, turnip greens, kale, and broccoli.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Science Daily and Summerbell et al. are set forth above. It is disclosed that when overall calorie consumption is account for, calcium not only helps to keep weight in check but also can be associated specifically with decreases in body fat (paragraph 1). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Science Daily does not indicate that the source of calcium is from salmon, tofu, spinach, turnip greens, kale, or broccoli. However, this deficiency is cured by the Dietary Supplement Fact Sheet.

The dietary supplement fact sheet indicates foods with sources of calcium include salmon, tofu, spinach, kale, turnip greens, and broccoli.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily, Summerbell et al., and the Dietary Supplement Fact Sheet and utilize other sources of calcium. One of ordinary skill in the art would have been motivated to utilize other sources of calcium because Science Daily indicates that vegetables can be used as non-dairy sources. Furthermore, it would provide consumers with more choices of sources of calcium, which would be beneficial for patient compliance.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Study: Calcium May Curb Weight Gain in Young Women ("Science Daily") in view of Summerbell et al. and in further view of McCarty et al. (US Patent No. 5914326).

Applicant Claims

Applicant claims that the caloric intake is in the range of about 2000 to about 2500 kcal per day.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Science Daily and Summerbell et al. are set forth above. Specifically, Science Daily teaches that administration of calcium in an amount of 1000

mg caused weight loss in women. Summerbell et al. teach that diets of milk caused weight loss in obese patients.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Science Daily does not teach that the caloric intake for an individual is in the range of about 2000 to about 2500 kcal per day. However, this deficiency is cured by McCarty et al.

McCarty et al. is directed to promoting weight and fat loss. The study of McCarty was directed to test the impact of a supplement regimen in conjunction with dietary and exercise advice on weight loss and physique modification in overweight volunteers. It is taught dietary recommendations correspond to a total daily caloric intake of 1,300 to 3,100 kcal daily which is depending on body size and the average recommended intake was about 2000 kcal daily (example 1).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Science Daily, Summerbell et al. and McCarty et al. and manipulate the caloric intake of the individual. One of ordinary skill in the art would have been motivated to manipulate the caloric intake depending on the body size of the individual as taught by McCarty et al. Since it was known in the art that methods of promoting weight and fat loss include the administration of a supplement in combination with exercise and dietary restrictions, it would have been obvious to one of ordinary skill in the art based on the teachings of Science Daily, Summerbell et al. and

McCarty et al. to administer calcium in combination with a reduced caloric intake to induce weight loss. Depending on the size of the individual more or less calories would be required on a daily basis.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting/Terminal Disclaimer

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The terminal disclaimer filed on April 3 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6384087 has been reviewed and are accepted. The terminal disclaimer has been recorded.

Claims 1, 5-6, 27-37, 41-44, 46-53, 55, 57, 59-62 and 64-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-15 of copending Application No. 10/827296. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a method comprising in combination, during a period of time administering therapeutically effective amount of calcium in an amount of about 773 mg per day to an obese individual suffering from at least Grade I obesity with a BMI values of about 25.0 and restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein the individual loses weight during the period of time.

Copending '296 claims a method of avoid health problems in an individual at risk thereof due to excess body weight and/or an excess of body fat, the individual suffering form at least Grade I obesity, comprising in combination during a period of time: administer to the individual one or more servings of a dairy product comprising a sufficient amount of dietary calcium of at least about 773 mg per day to induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue

in the individual, and maintaining the individual on a restricted caloric diet below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein the individual is a women and the one or more servings is at least about 57 servings of dairy per month.

Copending '296 does not claim specific sources of the calcium. The difference between the instant application and copending '296 is that the instant application claims specific types of calcium sources.

The relationship between the instant application and copending '296 is a genus-species relationship. Spinach, supplements, diary products, etc. are particular types of calcium sources. Therefore, both the instant application and copending '296 are directed to similar subject matter.

Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-6, 27-37, 41-44, 46-53, 55, 57, 59-62 and 64-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-17, 19-22 of copending Application No. 10/827307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '307 claims a method of including weight loss and/or increasing the metabolic consumption of tissue in an individual suffering from obesity, wherein obesity is selected from the group consisting of Grade I, Grade II, and Grade III obesity, wherein the method comprising in combination during a period of time administering to the obese individual one or more servings of one more calcium calcium-containing products where the one or more servings comprise an amount of dietary calcium of at least about 773 mg per day, sufficient to include with loss, and/or increase the metabolic consumption of adipose tissues, and restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day where in the individual is a women and the one or more servings comprise at least about 57 servings of dairy per month.

Copending '307 does not claim specific sources of the calcium. The difference between the instant application and copending '307 is that the instant application claims specific types of calcium sources.

The relationship between the instant application and copending '307 is a genus-species relationship. Spinach, supplements, diary products, etc. are particular types of calcium sources. Therefore, both the instant application and copending '309 are directed to similar subject matter.

Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed November 10 2008 are acknowledged. The rejections are maintained since applicant has not made any substantive arguments traversing the rejection.

Claims 1, 5-6, 28-37, 41-44, 46-53, 55, 57, 59-62, 64-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 23-24, 35-38, 41, 50, 55-58, 61-63 and 78-79 of copending Application No. 10017568 in view of Science Daily and McCarty et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '568 claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-$(OH)_2$-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue. A specific antagonist is calcium. The individual has Grade I, II, or III obesity.

Copending '568 does not claim the source of calcium, the amount of calcium nor the number of servings, or the caloric amount per day for the individual. However, these deficiencies are cured by Science Daily and McCarty et al.

Science Daily teaches that an effective amount of calcium to cause weight loss is 1000 mg per day. Calcium sources include milk, yogurt, cheese, vegetables, nuts, beans, and calcium supplements.

McCarty et al. teaches that in a method of promoting weight and fat loss, administration of supplement in combination with dietary restraint and exercise can cause weight loss. The daily caloric intakes should range from 1,300 to 31000 kcal daily depending on body size.

It would have been obvious to one of ordinary skill in the art to combine the teachings of copending '568, Science Daily, and McCarty et al. and utilize calcium in an amount of at least 1000 mg. One of ordinary skill in the art would have been motivated to utilize this amount as it is taught by Science Daily as an effective amount to cause weight loss. Furthermore, it would have been obvious to one of ordinary skill in the art to vary the amount of calcium to administer in order to optimize weight loss.

It would have been obvious to one of ordinary skill in the art to combine the teachings of copending '568, Science Daily, and McCarty et al. and vary the caloric intake of the individual. One of ordinary skill in the art would have been motivated to vary the caloric intake depending on the body size of the individual as taught by McCarty et al. Therefore, it would have been obvious to one of ordinary skill in the art to increase the caloric intake for higher weight individuals and lower the caloric intake for lower weight individuals.

Regarding the administration of at least 57 or 102 servings of dairy per month (instant claims 1, 10, 12, 19, 50, 61 and 69-71), the amount of calcium instant claimed

and that of Science Daily is the same (at least 1000 mg/day). Therefore, depending on the source of the calcium it would have been obvious to one of ordinary skill in the art to determine the appropriate number of servings to consume in order to reach the required daily amount of at least 1000 mg/day.

Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: The citing of this new non-statutory double patenting is due to the filing of amendment in the copending application, in which calcium was newly introduced in the pending claims as a species for use in the claimed method.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
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